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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of)
Charles CHAUVEAU et al.)
Serial No. : 09/830,946) Art Unit: 1616
Filed: November 3, 1999) Examiner: GOLLAMUDI, SHARMILA

For : IMPROVED FAST DESINTEGRATING TABLET.

DECLARATION UNDER RULE 132

To Honorable Commissioner of Patents and Trademarks
Washington, D.C.

Sir :

I, Noureddine NOURI of 10, boulevard de la République 06400 Cannes, France, do solemnly declare :

THAT I have been working with the firm ETHYPHARM since September 2nd, 1996 and that I held the position of Formulation Project Leader from January 1998 to December 2002;

THAT I am a named inventor on the present patent application n° 09/830,946 and that I am fully familiar therewith ;

THAT I have read and understood the Office Action of February 20, 2003 in connection with the present patent application ;

THAT the invention subject of the present patent application concerns multiparticulate tablets which are intended to disintegrate in contact with saliva in the mouth in less than 40seconds, without chewing, said tablets are called orodispersible tablets;

THAT Gowan (US5,876,759) discloses rapidly disintegrating oral formulations;

THAT the detailed embodiment described in Gowan as well as the example relate to wafers which can not be considered as similar to the orodispersible tablets according to the invention;

THAT Gowan's wafers do not contain disintegrating agent in addition to the carbohydrate;

THAT if, as indicating by the Examiner microcrystalline cellulose can be considered as a disintegrating agent in tablets, it is well known that in tablets, it acts also as a binder, a diluent or a flow-enhancer for pulverulent excipients,

THAT, for the person of skilled in the art, at low concentration of less of about 30% by weight of the total composition, microcrystalline cannot act as a disintegrating agent but as a binder;

THAT, according to Gowan, see in particular lines 26 to 36 of column 3, microcrystalline cellulose acts as a binder;

THAT there is no suggestion in Gowan to add a disintegrating agent;

THAT the orodispersible tablets according to the invention must contain a disintegrating agent in addition to the polyol with binding properties;

THAT Gowan's wafers and orodispersible tablets according to the invention present different structural and physical properties;

THAT according to Gowan, the hardness of the wafer must be at least 1.0 kp to present satisfactory friability;

THAT said hardness must not be above 3.0 kp in order to disintegrate in the oral cavity as indicated at lines 49-50 of column 7;

THAT on the contrary, orodispersible tablets according to the invention can present a hardness as high as 70N (7 kp), see page 15 line 16;

THAT the wafers according to Gowan present a diameter of 16mm and a of 360-440 mg;

THAT the tablets according to the invention could have the same diameter but preferably a smaller diameter and are heavier (700mg to 1400mg);

THAT consequently, disintegrating Gowan's wafers is easier than disintegrating tablets according to the invention;

THAT according to the present invention, without the presence of a disintegrating agent in the specified amount in addition to a polyol with binding properties, the disintegration of the tablet in less than 40 seconds would not be possible.

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 21, July 2003


Noureddine NOURI